IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM AND PRETRIAL ORDER NO.

Bartle, C.J. April 12, 2007

Audrey Deborer a/k/a Audrey DeBoer[1] ("Ms. Deborer" or "claimant") is a class member seeking benefits from the AHP Settlement Trust ("Trust"), which was established under the Diet Drug Nationwide Class Action Settlement Agreement with Wyeth[2] ("Settlement Agreement"). Based on the record developed in the show cause process, we must determine whether claimant has

1. The Trust refers to claimant as "Audrey Deborer," which is also how claimant's name appears on the Order to show cause. On the Pink Form submitted to the Trust by claimant's counsel, claimant's name also appears as "Audrey Deborer." The correct spelling of claimant's name, however, is "Audrey DeBoer," as reflected by claimant's signature on her Green and Pink Forms and on her Attorney & Client Contract.

2. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. Part I of the Green Form is to be completed by the claimant or the claimant's representative. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, Part III is to be completed by the claimant's attorney if he or she is represented. To obtain Matrix Benefits, a claimant must establish that there is a reasonable medical basis for his or her claim under the criteria set forth in the Settlement Agreement. Accordingly, a claimant may not recover benefits if the attesting physician's reading of

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3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period, or who took the drugs for 60 days or less, or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

the echocardiogram, and thus his or her accompanying Green Form answers, have no reasonable medical basis.

In April 2000, claimant submitted a completed Green Form to the Trust signed by her attesting physician Ramon Castello, M.D. Based on an echocardiogram dated June 2, 1998, Dr. Castello attested in Part II of her Green Form that she suffered from moderate mitral regurgitation and a reduced ejection fraction in the range of 50% to 60%. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $426,912.

In the report of claimant's echocardiogram, Harvey Feigenbaum, M.D., the reading cardiologist, stated that claimant had "[m]ild to [m]oderate [m]itral [r]egurgitation." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. The report did not indicate claimant's level of ejection fraction. An ejection fraction is considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%. See id. at § IV.B.2.c.(2)(b).

In March 2001, prior to the Trust's notifying claimant that her claim was selected for audit,[4] the Trust forwarded Ms. Deborer's claim for review by Judy Hung, M.D., one of its

4. The Trust did not notify Ms. Deborer that her claim was selected for audit until April 2001.

auditing cardiologists. In audit, Dr. Hung concluded that claimant's ejection fraction was greater than 60%. In July 2001, the Trust forwarded Ms. Deborer's claim for review by Keith B. Churchwell, M.D., also one of its auditing cardiologists.[5] In audit, Dr. Churchwell concluded that there was no reasonable medical basis for Dr. Castello's finding that claimant had a reduced ejection fraction. Dr. Churchwell determined that claimant's ejection fraction was "at least 65% or greater, aggressive, dynamic LV." Neither Dr. Hung nor Dr. Churchwell was asked to review claimant's level of mitral regurgitation, although both independently found it to be moderate.[6]

Based on Dr. Churchwell's diagnosis of a normal ejection fraction, the Trust issued a post-audit determination denying Ms. Deborer's claim. Pursuant to the Polices and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit ("Audit Polices and Procedures"), claimant contested this adverse determination and requested that the claim

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5. It is not clear why the Trust forwarded Ms. Deborer's claim to two different auditing cardiologists. In its Show Cause submissions, the Trust only refers to the audit conducted by Dr. Churchwell. The Trust, however, forwarded claimant the results of both audits.

6. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust did not contest the attesting physician's finding of moderate mitral regurgitation, the only issue is whether claimant has a reduced ejection fraction, which is one of the complicating factors needed to qualify for a level II claim.

proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7; Pretrial Order ("PTO") No. 2457, Audit Policies and Procedures § VI.[7] The Trust then applied to the court for issuance of an Order to show cause why Ms. Deborer's claim should be paid. On November 26, 2002, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 2656 (Nov. 26, 2002).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on March 18, 2003. Under the Audit Policies and Procedures, it is within the Special Master's discretion to appoint a Technical Advisor to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record.[8] See Audit Policies and

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7. Claims placed into audit on or before December 1, 2002 are governed by the Audit Policies and Procedures, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Rules for the Audit of Matrix Compensation Claims, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Policies and Procedures contained in PTO No. 2457 apply to Ms. Deborer's claim.

8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical (continued...)

Procedures § VI.J. The Special Master assigned Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant, and prepare a report for the court. The Show Cause Record and Technical Advisor's Report are now before the court for final determination. Id. at § VI.O.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had a reduced ejection fraction. See id. at § VI.D. Ultimately, if we determine that there was no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must confirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. at § VI.Q. If, on the other hand, we determine that there was a reasonable medical basis, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id.

In support of her claim, Ms. Deborer submitted a verified, supplemental opinion from Dr. Castello, who confirmed his previous finding that claimant had a reduced ejection fraction. He further explained that:

> It is important to note that upon a cursory review of the tape in question, even a trained cardiologist could mistakenly conclude that the ejection fraction is

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8.(...continued)
Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. See id.

> greater than 60%. It is my opinion to a reasonable degree of medical probability that the potential for such an excessively high misinterpretation is that the parasternal views and particularly the long axis views, are out of alignment or "off axis" in this particular study. This is a well-recognized pitfall in the assessment of ejection fraction with these studies and is due to misalignment in certain views due to the heart's movement or the alignment of the transducer by the cardiac sonographer.
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> A careful review of the Claimant's long axis and short axis views utilizing the beats that were not "off axis" clearly shows that the ejection fraction of this particular study is 50-55%.

Claimant argues that the auditing cardiologist misinterpreted her ejection fraction by relying on the parasternal views, which were "off axis." Claimant also argues that her attesting physician has reviewed her echocardiogram on numerous occasions, and, each time, he has concluded that her ejection fraction was between 50% and 55%. Claimant further asserts that her attesting physician reviewed the tape in the presence of two other qualified cardiologists, both of whom concurred with his finding of a reduced ejection fraction.[9] Finally, Ms. Deborer argues that, according to medical literature, the "standard error of measurement" for an ejection fraction is "+/- 5%." Thus, claimant contends that an ejection fraction measured as 65% could reasonably be read as being less than or equal to 60%, which meets the definition of a reduced

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9. In support of her claim, however, claimant submitted only an opinion from Dr. Castello.

ejection fraction for a mitral valve claim under the Settlement Agreement.

In response, the Trust disputes claimant's assertion that Dr. Churchwell's finding of an ejection fraction of 65% was a result of relying on "off axis" parasternal views. Conversely, the Trust argues that Dr. Churchwell evaluated claimant's ejection fraction in multiple views of her echocardiogram, including the apical views. The Trust also asserts that the standard for review in the show cause process is whether there is a reasonable medical basis for the claim, not which party can collect more opinions. The Trust further contends that Dr. Castello's supplemental opinion did nothing more than confirm his initial finding, which Dr. Churchwell previously found to have no reasonable medical basis.

Dr. Vigilante reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding of a reduced ejection fraction because her echocardiogram demonstrated a normal ejection fraction. In particular, Dr. Vigilante found that:

> The left ventricle was evaluated in the parasternal long axis view, parasternal short axis view, apical four chamber view, and apical two chamber view. Endocardial definition was well identified. There was vigorous and normal contraction of all segments of the left ventricle. Evaluation of the apical four chamber view demonstrated a left ventricular ejection fraction of 65%. This was noted on three cardiac cycles in the apical four chamber view.
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> It would not be possible for a reasonable echocardiographer to conclude that the ejection fraction in this study was in the range of 50% to 60%.

In response to the Technical Advisor Report, claimant argues that neither the auditing cardiologist nor the Technical Advisor considered the "universally-accepted deviation or standard of error of measurement" of five percentage points for an ejection fraction. Claimant argues that, as Drs. Churchwell and Vigilante concluded that her ejection fraction was 65%, there is a reasonable medical basis for her claim. Finally, claimant contends, without any support, that Dr. Vigilante simply made a "bold and baseless" assertion that there was no reasonable medical basis for her attesting physician's finding of a reduced ejection fraction.[10]

After reviewing the entire Show Cause Record before us, we find claimant's arguments without merit. First, we disagree with claimant that Dr. Vigilante's conclusion was a "bold and baseless assertion."[11] To the contrary, Dr. Vigilante provided a

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10. Claimant also argues that the Technical Advisor failed to address her contention that the parasternal views are "off axis," thus making her ejection fraction appear larger. We disagree. The Technical Advisor Report reflects that Dr. Vigilante specifically acknowledged this argument, but still found no reasonable medical basis for the attesting physician's finding of a reduced ejection fraction. Further, the Technical Advisor Report also reflects that Dr. Vigilante reviewed claimant's entire Show Cause Record.

11. According to claimant, the Technical Advisor's conclusion demonstrates "his own lack of credibility and questionable competence in this matter." As noted above, the Technical

(continued...)

detailed analysis in support of his conclusion that there was no reasonable medical basis for the attesting physician's finding of a reduced ejection fraction. Dr. Vigilante thoroughly reviewed claimant's echocardiogram and determined that her ejection fraction was 65% "on three cardiac cycles in the apical four chamber view." Claimant does not refute or address Dr. Vigilante's specific finding as to her level of ejection fraction. On this basis alone, claimant has failed to establish a reasonable medical basis for her attesting physician's finding of a reduced ejection fraction.

Instead, claimant argues that there should be an automatic five percentage point "standard of error" in the measurement of an ejection fraction in determining whether there is a reasonable medical basis for an attesting physician's finding regarding a claimant's ejection fraction. We reject this argument. Any "standard of error" in the measurement of an ejection fraction is encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's finding of a reduced ejection fraction cannot be medically reasonable where the

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11.(...continued)
Advisor's detailed findings and conclusions reveal the exact opposite. Further, the unquestioned qualifications of the court's Technical Advisors, including Dr. Vigilante, were established previously when we approved the appointment of the Technical Advisors, without any objections despite notice and an opportunity for objections to be raised. See PTO No. 3212 (Jan. 14, 2002).

auditing cardiologist and Technical Advisor concluded that claimant's echocardiogram demonstrates an ejection fraction of 65%. To conclude otherwise would allow a claimant with an ejection fraction of 65% to recover Matrix Benefits. This result would render meaningless the standards established in the Settlement Agreement.[12]

For the foregoing reasons, we conclude that claimant has not met her burden in proving that there is a reasonable medical basis for finding that she had an ejection fraction in the range of 50% to 60%. Therefore, we will affirm the Trust's denial of Ms. Deborer's claim for Matrix Benefits.

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12. This is particularly true in the context of Ms. Deborer's claim where the Technical Advisor specifically concluded that "[i]t would not be possible for a reasonable echocardiographer to conclude that the ejection fraction in this study was in the range of 50% to 60%."

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PRETRIAL ORDER NO.

AND NOW, this 12th day of April, 2007, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the final post-audit determination of the AHP Settlement Trust is AFFIRMED and that the Level II Matrix claim submitted by claimant, Audrey Deborer a/k/a Audrey DeBoer, is DENIED.

BY THE COURT:

/s/ Harvey Bartle III
C.J.